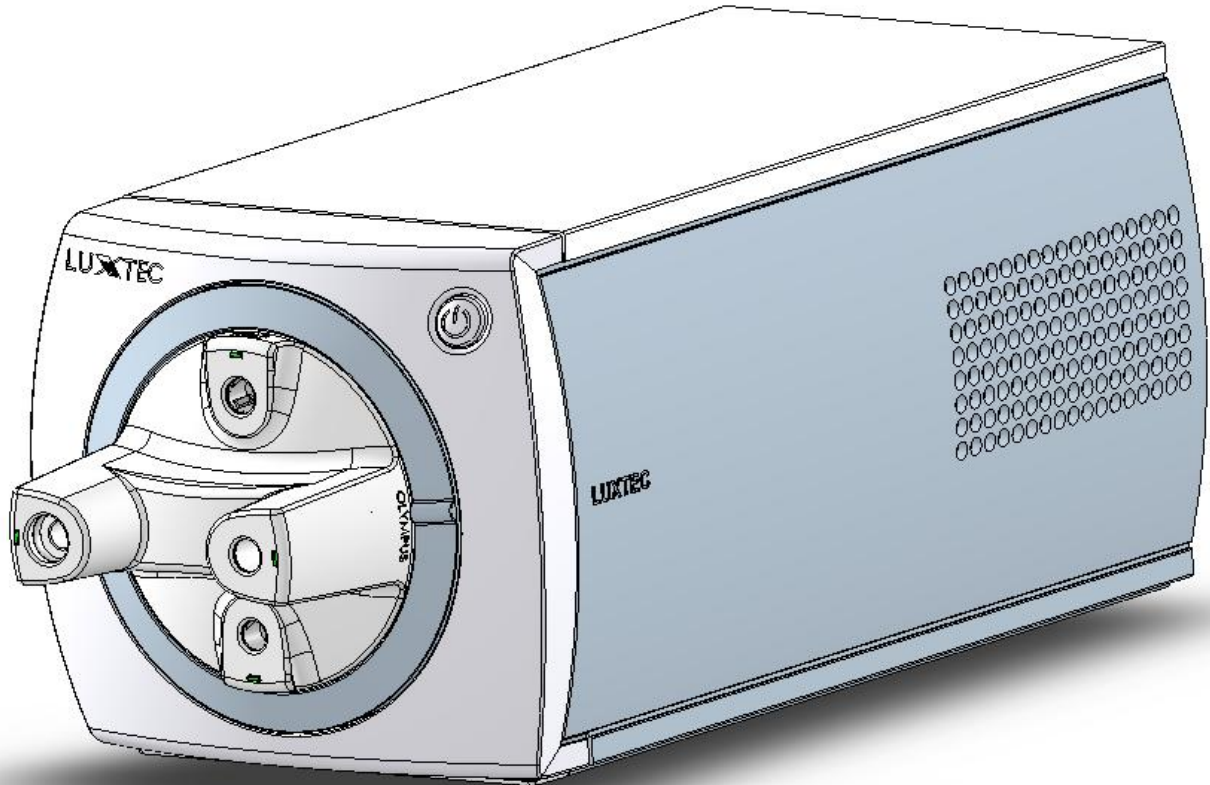




User Manual for CLX-T Xenon Light Source



ENGLISH

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TABLE OF SYMBOLS

Found on Light Source



Attention: Consult
Accompanying Documents



Type CF Equipment



Stand-by



High Voltage



Fuse



ETL listed



High Temperature



“ON” (power)



CE marking of conformity



Equipotentiality



“OFF” (power)

GENERAL WARNINGS

FIRE HAZARD: **Do Not** drape or cover the light source while it is operating

EXPLOSION HAZARD: **Do Not** use in the presence of flammable anesthetics.

ELECTRIC SHOCK HAZARD: **Do Not Open** the light source if it is not functioning properly or if damage is apparent (such as case damage or loose screws). Refer to the Repair and Return Section of this Manual.

- The User of this equipment should carefully read the Users Manual and be familiar with the set-up, use, and care of the light source before using it. The instructions in the Users Manual should be followed carefully with special attention to warnings and control features on the light source. The Users Manual should be readily available to users and other appropriate personnel.
- Before each use ensure that the light source is not damaged and is operating properly. Ensure that cooling vents and fans are free of obstruction.
- The light source generates high intensity light that can heat objects in its path. This light can cause flammable materials to burn or cause burns to skin. Prevent flammable materials from coming into close proximity with the output of the light source and light cable.
- The light emitted from the light source and the light cable can cause eye damage if viewed directly for more than momentary periods of time. Do not look directly into the light source or the cable. Do not point the light cable at another person's eyes. For this reason this product must not be used in ocular surgery or in any surgical procedure requiring direct illumination of the eye.
- Avoid extreme heat or jarring of the light source to maintain the integrity of the Xenon lamp. Refer to the Xenon Lamp Replacement Section of this Manual when replacing the lamp or removing it for any reason.
- Follow the instructions of other manufacturers equipment when using them in conjunction with this light source.
- Before any service, disconnect the power cord from the main outlet.

Medical Electrical Equipment such as the CLX-T Light Source require special precautions regarding electromagnetic compatibility or EMC. These precautions are defined on pages 11 thru 14 of this Users Manual. The CLX-T must be installed and put into service according to the EMC information provided.

The leakage current of medical electrical devices can be additive. When using the CLX-T in combination with other medical electrical devices, such as endoscopes and/or endoscopy accessories, the leakage current should be verified to ensure it continues to meet requirements.

OVERVIEW

Indication for Use

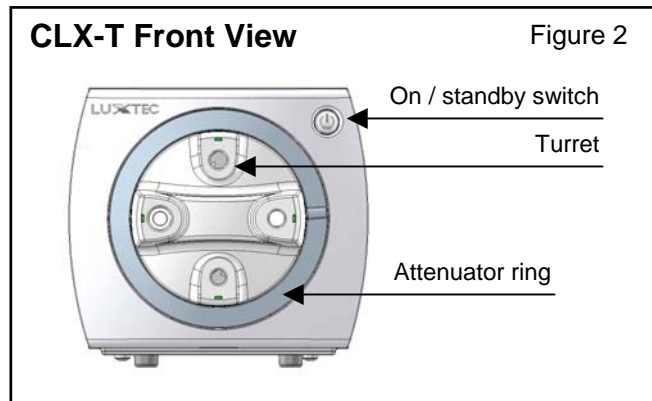
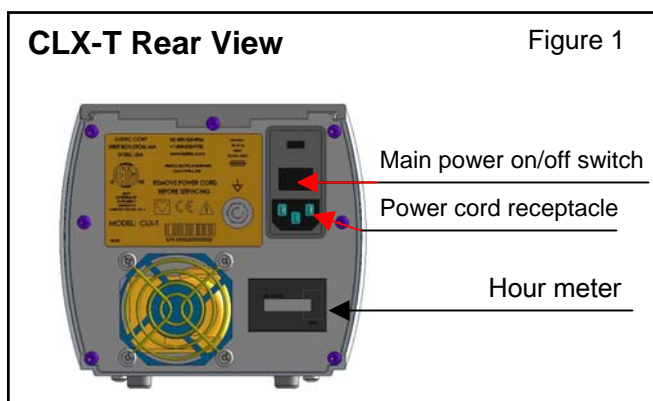
This device is designed to supply high-intensity white light to a fiber optic cable for illumination of a surgical field or other area of examination or operation. The Light Source should never be used in ocular surgery or in a surgical procedure requiring direct illumination of the eye.

The CLX-T delivers white Xenon light. The lamp can be easily replaced by the user without special tools.

The rear panel, *main power on/off rocker switch*, is located on the back of the CLX-T. See Figure 1. The front panel push button, *on / standby switch*, is used to select lamp on or lamp standby. See Figure 2.

The intensity of the light output is controlled manually by rotating the attenuator ring, clockwise to increase intensity, counter-clockwise to decrease intensity.

The turret assembly consists of Wolf, ACMI, Storz and Olympus light guide ports. The turret assembly should be rotated to the 12 o'clock position to select the proper port for your light guide. A green indicator shows which port is active when the unit is "on".



Inspection Before Use

The CLX-T light source comes with a hospital grade power cord. Please verify that both the light source and the power cord have been received undamaged.

All fiber optic light guides should be properly cleaned and sterilized prior to first time use. See light guide manufacturer's manual for information.

Warnings

FIRE HAZARD: DO NOT DRAPE OR COVER THE LIGHT SOURCE WHILE IT IS OPERATING.

Explosion Hazard: Do not use in the presence of flammable anesthetics, liquids, vapors, gases or dusts.

Electric shock hazard: If unit is not functioning properly, DO NOT OPEN.
Please refer to the Repair and Return Section of this Manual.

Use care not to point any light guide directly at the eye while operating the Light Source.

Keep cooling and fan vents free of obstructions.

Do not use or store liquids on or above the Light Source.

When Light Source is not in use, turn off the power switches on both the front and the back of the CLX-T.

Setting Up

Before turning power on, make sure the unit is plugged into any standard 100V to 240V 50/60Hz (as appropriate) three-conductor outlet. Grounding reliability is guaranteed only when connected to a "hospital grade" receptacle.

OPERATION

Controlling Lamp Operation

The main power on/off switch is used to power the unit on or off. See Figure 3.

The on / standby switch is used to select lamp on or lamp standby. See Figure 4.

The light source requires both the main power and the standby switches to be in the “on” state for the lamp to operate.

When the lamp starts operating, there is a brief clicking sound, which is normal. If the main power on/off switch is used to toggle lamp operation, leaving the standby switch in the “on” state, then there will be a short delay (3 or 4 seconds), after turning the main power switch to the “on” position, before the lamp will energize. This delay will not occur when the standby switch is used to control the lamp.

Note that if the light source is left in standby, with power applied, with the main power on/off switch in the “on” position and the on / standby switch in the standby state, the unit will consume a small amount of power and be slightly warm to the touch. This is normal and permits the lamp to quickly energize with the on / standby switch.

When the lamp is operating the active port indicator will illuminate. See Figure 5.

Light Attenuation

The CLX-T has a manually operated light intensity ring to control the desired light output level. To increase the light output, rotate the ring clockwise until the desired level is reached. See Figure 5.

Turret Operation

Rotate the Turret (Fig. 5) to select the appropriate port for your light guide. The turret has ports for Wolf, ACMI, Storz and Olympus light guides. The active port shows a green indicator light when the unit is “on”. The active port is at the 12 o'clock position.

Each port has a light blocking feature. So when a cable is removed no light is emitted. Therefore, it is important to note the active port so that the proper cable is connected to the correct port.

Figure 3

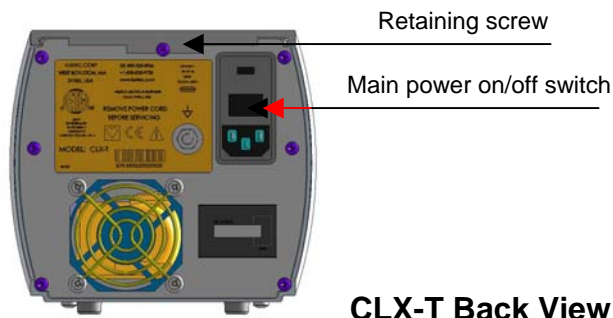


Figure 4

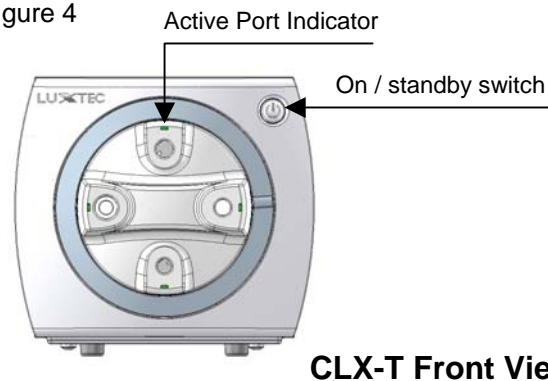
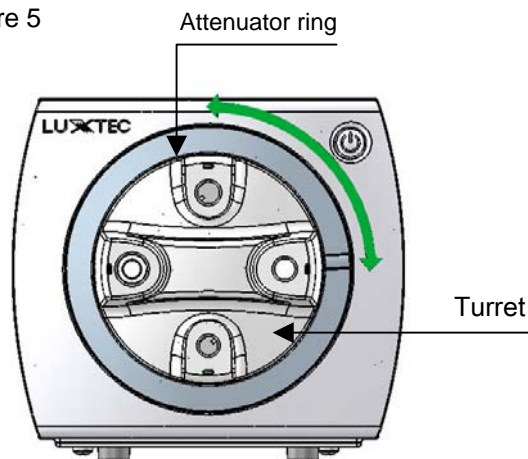


Figure 5



XENON LAMP REPLACEMENT

Warnings:

Disconnect the light source from main power and allow the equipment to cool before handling the Xenon lamp. Use protective eye, face, and hand equipment when handling the Xenon lamp. *Please know that Xenon lamps have been known to explode. The chance of this happening when the lamp is handled properly is very low. The chance of injury if the lamp should explode are very high if the proper precautions are not taken. The chance of a lamp failure while the light source is not in operation is very rare. Each lamp is tested thoroughly during manufacture to ensure against failure.*

Figure 6

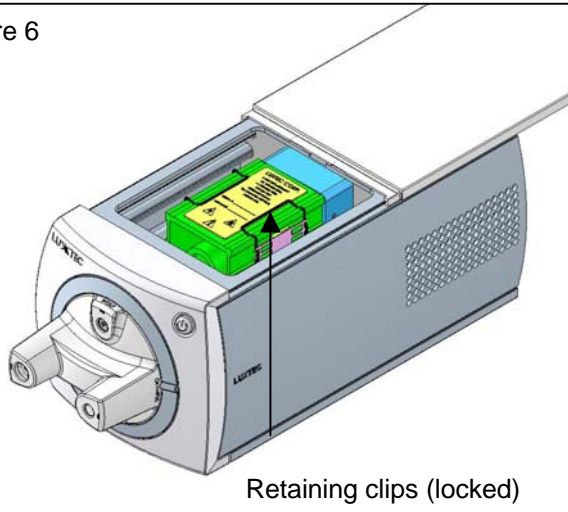
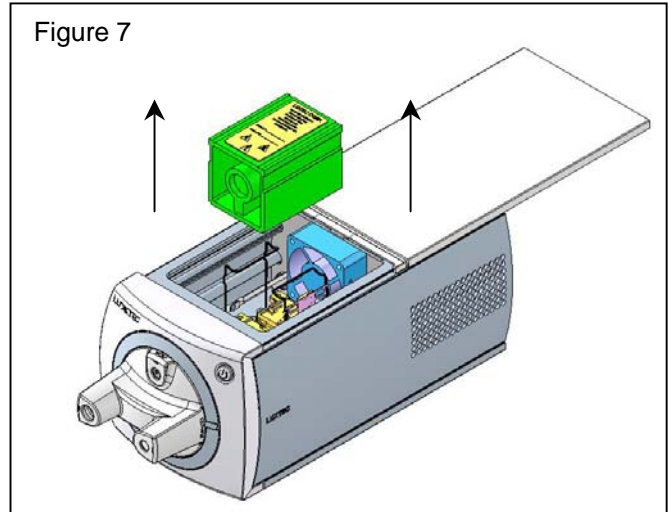


Figure 7



It is recommended that the Xenon lamp (part no. 00-1187) be replaced at 500 hours of usage. Lamp usage is monitored by the hour meter on the rear panel of the CLX-T. When replacing the lamp, the date and number of hours should be recorded to track the aging of the new lamp.

To remove the lamp:

1. Make sure the main power on/off switch is turned off. Disconnect the power cord.
2. Allow the unit to cool down for a minimum of 15 minutes before replacing the lamp. The lamp may represent a burn hazard if not allowed to cool sufficiently prior to servicing the unit.
3. Remove the retaining screw located at the back of the CLX-T. See Figure 3. The retaining screw also acts as a power interlock switch. Once the screw is removed the unit cannot be turned on. The screw must be replaced prior to turning the unit on.
4. Slide the top cover of the CLX-T towards the back of the unit. See Figure 6.
5. Unlock the lamp retaining clips holding the lamp in the CLX-T. Grasp and pull the lamp straight up. See Figure 7.

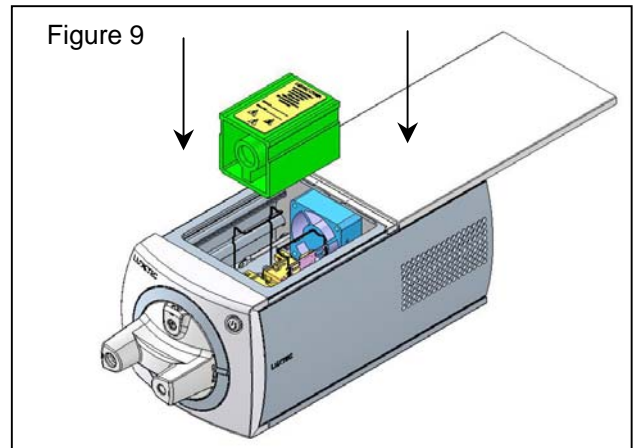
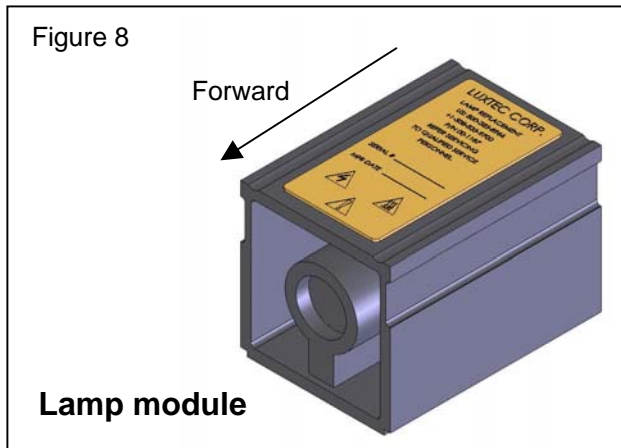
XENON LAMP REPLACEMENT

To replace the lamp:

1. Orient lamp to face forward. See Figure 8. Lower lamp into the CLX-T with lamp against fan. See figure 9. The lamp receptacles must engage with lamp base plugs. Press firmly into place to seat lamp.

Note: Do not touch lamp glass window.

2. Snap the lamp retainer clips, located on each side of the lamp, onto the top of the lamp. The lamp is now in a locked position. See Figure 6.
3. Fully slide the top cover of the CLX-T forward. Install the retaining screw (Figure 3) using a screwdriver.
4. Connect power cord to the back of the CLX-T. Set main power on/off switch to the "on" position, then press on / standby switch to turn the unit "on".
5. Connect a fiber optic cable to verify the unit emits light.



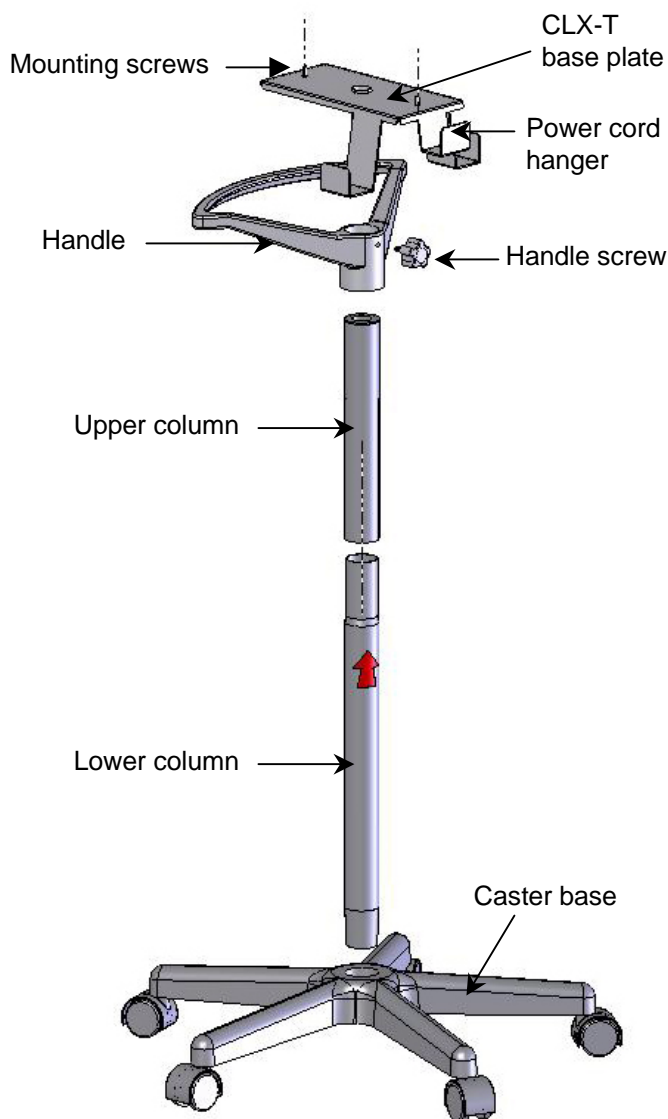
Lamp disposal:

No disposal restrictions are known for the Xenon lamp. User should check and follow any applicable federal, state and/or local regulations.

To dispose of Luxtec Xenon lamps, simply break the fill tab to release any remaining gas and then dispose of the lamp with no environmental concerns. Luxtec lamps are constructed entirely of metal, sapphire and ceramic. No organic (carbon-based) materials, mercury, rare-earth elements, or any other materials with disposal problems are used in the construction of our lamps. The Xenon fill gas is an inert gas and is non-toxic.

OPTIONAL FLOOR STAND INSTALLATION

Figure 8



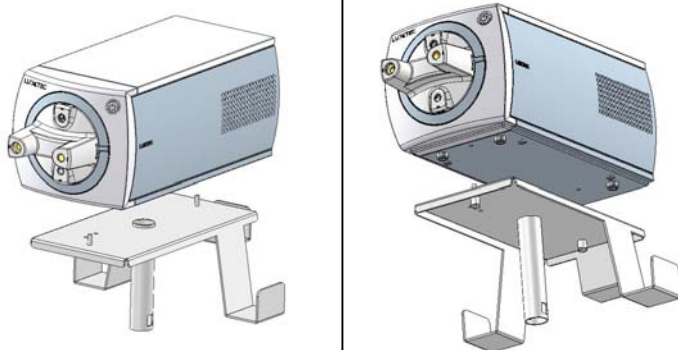
There are four (4) parts to the floor stand assembly: See Figure 8.

1. Caster base
2. Two-piece column
3. Light source base with cable hangers
4. Handle

Floor stand assembly instructions:

1. Assemble the column. Note arrow on the lower column must point up. Slide the upper column over the arrow end of the lower column. Seat firmly.
2. Insert assembled column into base. Seat firmly.
3. With the handle screw positioned at the top of the handle, slide the handle onto the upper column so there is about 5 inches (13 cm) of space between the handle and the top of the column. Tighten handle screw to hold in place.
4. Fully insert post of the CLX-T base plate into plastic bushing on top of upper column.
5. Loosen handle screw and position handle opposite power cord hanger. Adjust height as preferred by user, and firmly secure handle screw.
6. Secure CLX-T to base plate by aligning mounting screws to screws holes on bottom surface of CLX-T and tighten. See Figure 9.

Figure 9



EQUIPMENT & PARTS LIST

To place an order, contact your local Luxtec distributor or call Luxtec Customer Service at 800-325-8966 (USA) or +1-508-835-9700 (International).

Light Source

00-CLX-T	CLX-T, Xenon light source
850411	User Manual for the CLX-T

Lamp

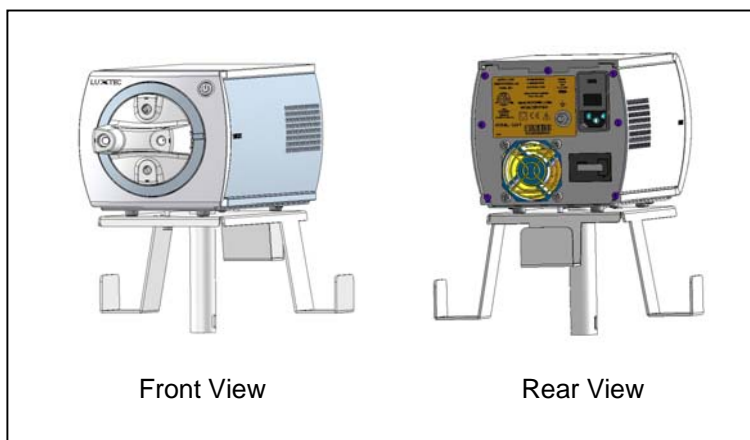
00-1187	CLX-T Lamp replacement module
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Power Cords

601949-AUSTL6M	Australian Power Cord 6m
601949-EUR6M	European Power Cord 6m
601949-UK6M	UK Power Cord 6m
601949-US6.1M	Hospital Grade USA Power Cord 20'

Other parts

005418	CLX-T floorstand bracket (top base only)
601915	Screw, 6-32 x 0.5"
601919	Fuse, 3.15A 250VAC, 5x20mm, Slo-Blo IEC Standard



TROUBLESHOOTING

Problem	Cause	Action
No light output	Cable not installed Both switches are not "on" Power not applied to the unit Attenuator closed Blown fuse	Install cable to open light blocking feature Turn main power switch on/off and on/standby switch "on" Ensure the power cord is connected to a live, hospital-grade, receptacle Rotate attenuator clockwise Replace fuse as indicated in maintenance section
No light output and unit is making clicking sound	Lamp is too old or is defective A lamp is not installed	Replace/Install lamp. See lamp replacement section of this user manual
Reduced light output	Attenuator mis-positioned Aged or defective lamp Headlight or fiber optic light guide is damaged	Rotate attenuator Replace lamp Check or replace faulty component
Unit feels warm when not on	Main power switch is on (Figure 3)	This is normal when main power switch is on and stand by switch is off
CLX-T enclosure is overheated	Possible fan failure	Return the unit (See Return and Repair section of this user manual)

MAINTENANCE AND CLEANING

Maintenance:

If the Light Source does not operate properly when connected to a grounded receptacle, disconnect the power cord and check the fuse (see below). Do not attempt to repair the unit if the lamp fails in use. Turn off the unit and allow it to cool for at least 15 minutes, then try to restart the unit. If the lamp still fails to illuminate, it may need to be replaced. If you still experience difficulties, return the unit to Luxtec or an authorized distributor for evaluation.

To replace the fuse:

The fuses for the Light Source are located in the power entry module in the rear of the unit. Remove the power cord from the unit. Using a small flat head screwdriver, open fuse access cover then pry out the red plastic fuse holder from the power entry module. Check to see if the fuses are blown. If necessary, replace the fuse(s) with a new one of the same rating (Fuse 3.15A, 250VAC, 5x20 mm, Slo-Blo, IEC Standard, Luxtec part number 601919). After replacing fuse(s), push the red plastic fuse holder back into the power entry module and snap access cover close. Plug the cord back into Light Source and re-test the unit.

Cleaning:

Allow unit to cool for at least 15 minutes prior to cleaning.

The Light Source exterior can be cleaned and disinfected using 70% isopropyl alcohol. Unplug the power cord before cleaning. Allow 5 minutes for alcohol to evaporate before reconnecting to power. Use a vacuum cleaner and a soft brush to remove visible dust accumulation from fan and vent holes whenever necessary and always when replacing the lamp.

SPECIFICATIONS

Lamp

Type	Xenon Short Arc Lamp
Wattage	150 Watts
Lamp life	500 Hours

Light Source

Dimensions	14.6"L x 6.2"W x 5.9"H (370mm L x 157mm W x 150mm H)
Weight	9.2 lbs. (4.2kg)
Power Input	100~240VAC 50-60 Hz \pm 10%
Fuses (2)	3.15A, 250VAC, 5x20 mm, Slo-Blo, IEC Standard
Power Consumption	225 Watt nominal
AC Power Leakage	Leakage current to chassis (with ground wire intact), less than 100 micro amps Leakage current to chassis (with ground wire interrupted), less than 500 micro amps
Classification	Type CF, Class 1, IEC 60601-1
Conducted and radiated emissions	Class B, IEC 60601-1-2
PFC Conformance	Harmonics and Flicker IEC1000-3-2 and IEC61000-3-3
Environment:	
Storage	0°C - 50°C (32° - 122°F) 10-85% Relative Humidity Non-Condensing
Operating	5°C – 40°C (41° - 104°F) 10-85% Relative Humidity Non-Condensing

Electromagnetic Compatibility (EMC) User Information

WARNING: Medical Electrical Equipment, such as the CLX-T Light Source, needs special precautions regarding Electromagnetic Compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in the following tables.

WARNING: Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

WARNING: The CLX-T Light Source should not be used adjacent to or stacked with other equipment. If this becomes necessary the CLX-T should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The EMC tables and other guidelines below provide information to the customer or user that is essential in determining the suitability of the CLX-T Light Source for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the CLX-T Light Source to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.

Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems		
The CLX-T Light Source is intended for use in the electromagnetic environment specified below. The customer or user of the CLX-T Light Source should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Enforcement – guidance
RF Emissions CISPR 11	Group 1	The CLX-T Light Source uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The CLX-T Light Source is suitable for use in all establishments including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Complies or Not applicable	Complies
Flicker IEC 61000-3-3	Complies or Not applicable	Complies

Electromagnetic Compatibility (EMC) User Information

Guidance and Manufacturer's Declaration—Immunity All Equipment and Systems			
The CLX-T Light Source is intended for use in the electromagnetic environment specified below. The customer or user of the CLX-T Light Source should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Electrical Fast Transient/burst IEC 61000-4-4	±2kV on AC Mains	±2kV on AC Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CLX-T Light Source requires continued operation during power mains interruptions, it is recommended that the CLX-T Light Source be powered from an uninterruptible power supply or battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.

Electromagnetic Compatibility (EMC) User Information

Please note: The CLX-T light source has been successfully tested to IEC 60601-2-25. The CLX-T was in the presence of an electrical-surgical generator, ESG, generating a field strength of between 18 and 23 V/m. During the testing the energized probes of the ESG were at a distance of 6" from the CLX-T and the ESG was energized in the cut and coagulate modes. The functioning of the CLX-T was not effected by exposure to this energy. The results of this testing are available from Luxtec.

Guidance and Manufacturer's Declaration – Emissions Equipment and Systems that are <u>NOT</u> Life-Supporting			
The CLX-T Light Source is intended for use in the electromagnetic environment specified below. The customer or user of the CLX-T Light Source should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	V1 = 3 Vrms	Portable and mobile RF communications equipment should be separated from the CLX-T Light Source by no less than the recommended separation distances calculated/listed below: $D = 1.17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1 = 3V/m	$D = 1.17\sqrt{P}$ 80 to 800 MHz $D = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum power rating in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Electromagnetic Compatibility (EMC) User Information

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the CLX-T Light Source Equipment and Systems that are <u>NOT</u> Life-Supporting			
The CLX-T Light Source is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the CLX-T Light Source can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the CLX –T Light Source as recommended below, according to the maximum output power of the communications equipment.			
Maximum Output Power (Watts)	Recommended Separation Distances for the CLX-T Light Source (meters)		
	150 kHz to 80 MHz	80 to 800MHz	800 MHz to 2.5 GHz
	$d = 1.17\sqrt{P}$	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$
0.01	0.12	0.12	.023
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

PRODUCT WARRANTY

Luxtec warrants that the CLX-T light source (except the lamp) shall be free from defects in material and workmanship under normal use and service for a period of three (3) years from the date of shipment from Luxtec. Luxtec's sole and exclusive liability under the warranty shall be, at Luxtec's option, either to repair or to replace any component which fails during the warranty period due to any defect in workmanship or material F.O.B. factory if:

1. Customer promptly reports such defect to Luxtec in writing,
2. If requested by Luxtec, customer returns equipment to Luxtec at the customer expense and,
3. Upon inspection, Luxtec finds the equipment to be defective.

This warranty is contingent upon normal and proper use of the equipment. It does not cover equipment modified without the written approval of Luxtec, subjected to unusual physical or electrical stress, altered with non-Luxtec parts or damaged during shipment back to Luxtec. This warranty is non-transferable unless authorized in writing by Luxtec.

Luxtec reserves the right to make design changes on its products without liability to incorporate said change in Luxtec products previously designed or sold.

Upon receipt of the product, it should be carefully inspected. If any defect is discovered, Luxtec must be notified immediately.

REPAIR AND RETURN

This device must be clean of all blood or other organic material prior to returning to Luxtec. Luxtec reserves the right to return unrepaired any equipment that is contaminated with blood or other organic material.

Warranty Service and Repair:

To obtain service under warranty or return product for repair, the customer should contact your local Luxtec distributor or call Luxtec Customer Service at (800)325-8966 (US only) or +1-508-835-9700.

Information contained in this manual is subject to change without notice.

Luxtec Corporation declares that this product meets the
Essential Requirements specified in Annex 1
of the Medical Device Directive (MDD).

LUXTEC



Declaration of Conformity

Manufacturer: Luxtec
99 Hartwell Street
West Boylston, MA 01583 USA
(800) 325-8966 (USA only), (508) 835-9700
FAX (508) 835-9976, info@luxtec.com

Type of Equipment: Medical Device

Model Name: CLX-T Light Source

Council Directive: Medical Device Directive 93/42/EEC,
Classification: Class I (rule 1, Annex IX),
Self-Declaration of Conformity (Annex VII)

EU Classification: Class I according to Rule 12, Annex IX

CE Mark first applied: June 2007

Authorized EU Representative:
Medical Products International Europe, B.V.
Schutweg 13 a
5145 NP Waalwijk, The Netherlands
Telephone: +31 (0) 416 563 754
FAX: +31 (0) 416 563 926

I, the undersigned, hereby declare that the medical device specified above complies with the Essential Requirements of EC Directive 93/42/EEC for a Class I medical device.

Signature: 
Rita Wadleigh, Quality and Regulatory Manager

Date of original Declaration: June 2007
Date of this revision: June 2007